Tackling the Burden of Substandard and Falsified Medicines and Health Technologies in Somaliland and Somalia

Abstract

Background: The problem posed by the substandard and falsified (SF) medicines is a rising global challenge. WHO estimates that sales of SF medical products in low- and middle-income countries is around US$ 30 billion whereby 1 in 10 medical is substandard or falsified.

Objectives: The purpose of this article was to enlighten the actions by the Somali NRA to tackle the scourge of SF medicines in Somalia.

Methods: The literature was reviewed on the topic and evidence from othersources were incorporated including reports of post-marketing surveillance surveys, assessments at national and regional levels, as well as author's experiences.

Findings: The medicines regulatory capacity is weak in Somaliland and Somalia, where only 16% of total indicators for the regulatory system was in place as per WHO/IGAD rapid benchmarking of the National Regulatory Authority (NRA) in 2017, increasing the risk of circulation of SF medicines in the local private sector dominated and exclusively import relied pharmaceutical supply chain. Key actions by the NRA to address this problem include: regulatory reliance mechanisms such as using the WHO PQ/EUL for emergency authorization of vaccines, i.e. COVID-19 vaccines, enhanced licensing procedures, information exchange with NRAs in the region as well as technical collaboration with WHO.

Conclusion & Recommendation: However, a lot has to be done and considering the weak laboratory capacity and the porous national borders, the risk of local circulation of SF medicines is high and swift actions are needed to ensure access to safe and quality medicines and health technologies in Somaliland and Somalia.

Keywords: substandard and falsified (SF) medicines, WHO, medicines quality monitoring (MQM), pharmaceutical supply chain

1. **Introduction**

"The history of drug counterfeiting dates back to centuries and is considered as one of the oldest crimes in human history"(1). "The problem posed by the substandard and falsified (SF) medicines is a rising global challenge. Substandard medical products are authorized medical products that fail to meet either their quality standards or their specifications, or both, whereas, falsified medical products are those that deliberately/fraudulently misrepresent their identity, composition or source"(2). "WHO estimates that sales of SF medical products in low- and middle-income countries account on the order of US$ 30 billion"(3)

Type of product	Number of Member States reporting	Total no. of product reports	Percentage of all products reported to database [a]
Anaesthetics and painkillers	29	126	8.5
Antibiotics	46	244	16.9
Cancer medicines	19	100	6.8
Contraception and fertility treatments	19	29	2.0
Diabetes medicines	7	11	0.8
Heart medicines	22	75	5.1
HIV/hepatitis medicines	9	43	2.9
Lifestyle products [b]	37	124	8.5
Malaria medicines	26	286	19.6
Mental health medicines	19	45	3.1
Vaccines	11	29	2.0

[a] Since only selected products are reported in this table, the percentages in this column do not add up to 100%. A table showing the breakdown of all reports using the anatomical therapeutic chemical classification is provided in the Annex to the main report.

[b] So-called lifestyle products include products for cosmetic use, erectile dysfunction, body-building and dieting.

*Figure 1*Examples of Substandard and Falsified Products Reported to the GSMS (2013-2017), WHO-cited (3).

"An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified"(4). "The U.S. Pharmacopeial Convention (USP) reported that a total of 848 samples out of 15, 063, representing 5.6% of total samples, failed the quality test from results of data collected from medicines quality monitoring (MQM) activities spanning the period of 2003–2013 in 17 countries of Africa, Asia, and South America"(5). "SF medicines are danger to the public health and are associated with detrimental health and socio-economic implications. WHO's report of the situation of counterfeit (fake) medicines in WHO regions

for Africa and East Mediterranean revealed that 20 of the participating countries in the survey reported to have carried out seizures of counterfeit medicines"(6). "IMPACT stakeholders estimate proportions ranging from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area"(7)

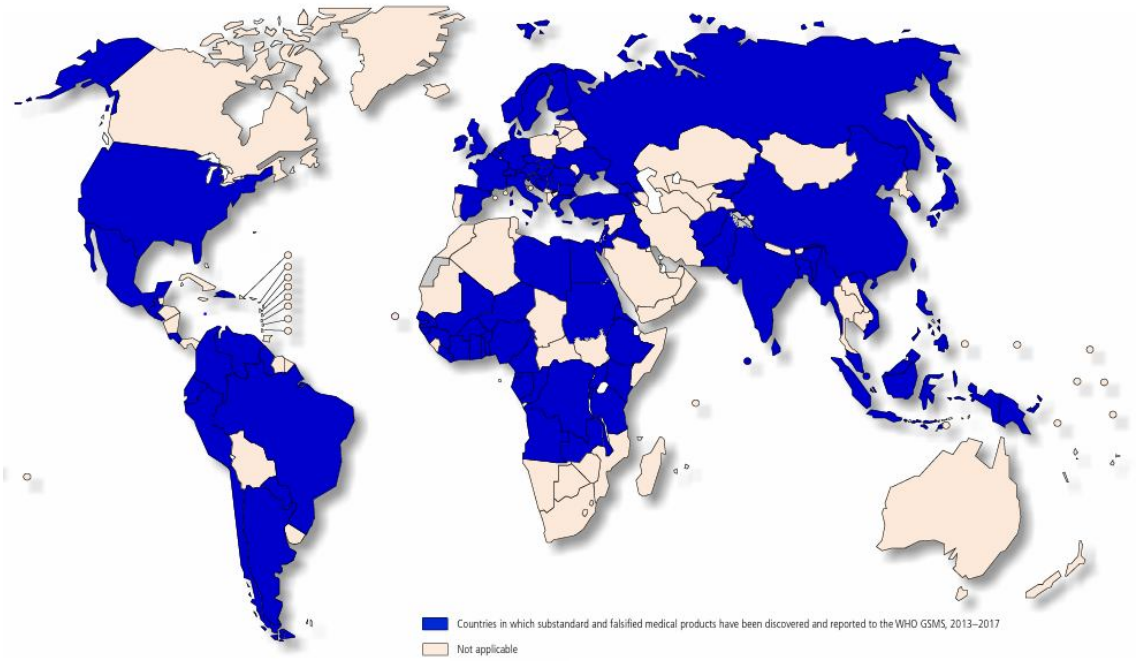

Figure 2 Countries which have reported substandard and falsified medical products to WHO Global Surveillance and Monitoring System, 2013-17;*WHO global surveillance and monitoring system for substandard and falsified medical products*

"It is difficult to quantify the extent of the problem, but in some areas of Asia, Africa and Latin America, counterfeit medical products can form up to 30% of the market"(7) "The United States' Food and Drug Administration (FDA) issued an alert about a counterfeit antiretroviral medicine and the UK officials seized 5000 packets of counterfeit flu medication oseltamivir in 2007 and 2006 respectively"(7).

"There are many reports about the detection SF medicines in the African Region. Forty-two percent of all reports to the WHO Global Surveillance and Monitoring System on SF medical products reported between 2013 and 2017 came from Africa, highlighting the magnitude of the problem"(8). "The Kenyan Pharmacy and Poisons Board (PPB) has issued an alert over a suspicious batch of counterfeit breast cancer treatment drug, Herceptin 440mg (Trastuzumab 440mg), detected in the market in 2024"(9). "Recently, a cluster of cases (*n*=78) of AKI among young children due to poisoning from Diethylene Glycol (DEG) that contaminated children's syrup-based medications was reported in Gambia, a West African country"(10). In January 2023, WHO issued report that over the past "preceding" four months, countries have reported on several incidents of over-the-counter cough syrups for children with confirmed or suspected contamination with high levels of diethylene glycol (DEG) and ethylene glycol (EG) (11) The cases were from at least seven countries, associated with more than 300 fatalities in three of these countries(11)Angola reported falsified artemether-lumefantrine and albendazole tablets in 2012, both medicines containing no active ingredient in them (12)Study on the quality of antimalarials in eight countries in Africa reported that the Non-QAACT (Quality Assured Artemisinin based Combination

Therapy) accounted for 20% of the market share in the private sector in Kenya, followed by Benin and Uganda (19%), Nigeria (12%) and Zambia (8%)(13)

Figure 3 Counterfeit and substandard pharmaceuticals shown by the Tanzanian Food and Drug Administration (TFDA) to the media; Petro Karungamye; https://doi.org/10.1016/j.fsir.2022.100302

2. Health and Socio-economic Impact of Substandard & Falsified Medicines

Substandard and falsified medicines (SF) have dire health and socio-economic impact and poses a global challenge. The health implications include therapeutic failure, drug resistance, serious morbidities or even death of the exposed. In 2004, fake medicines led to a trail of death in Argentina where a healthy 22-year-old woman, living in Viedma, Argentina, who had mild anaemia was given injections of an iron-based preparation, she became very sick and died of liver failure after receiving the seventh of a 10-injection treatment(7)

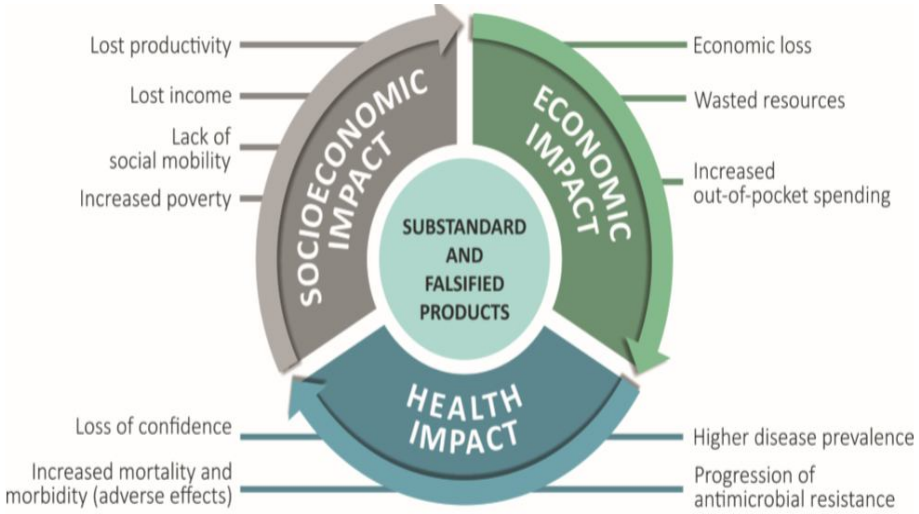

Figure 4 Impact of SF Medicines, WHO 2017; Licence: CC BY-NC-SA 3.0 IGO.

"The channels through which SF medicines can have an impact on a population's health, economic, and social status are manifold"(14) "A systematic review of 265 studies comprising 400 647 drug samples and meta-analysis of 96 studies comprising 67 839 drug samples reported data on the estimated economic impact were limited primarily to market size and ranged widely from $10 billion to $200 billion"(15). In the case of infectious diseases, treatment failure may also increase the risk of transmission to other individuals(16).

"The WHO commissioned model for the impact of substandard and falsified (SF) medicines on childhood pneumonia, which was developed by the University of Edinburgh, estimated that based on 10% prevalence of SF antibiotics, up to 72, 430 deaths from childhood pneumonia can be attributed to the use of the SF antibiotics that have reduced antibiotic activity, which can increase up to 169, 271 deaths if the antibiotics have no activity"(17).

Prevalence of substandard and falsified products (%)	**Number of excess deaths in most likely scenario** (two-fold increase in CFR)	**Number of excess deaths in alternative scenario** (four-fold increase in CFR)
1	8 688	18 372
5	37 018	85 438
10	72 430	169 271

Figure 5Impact of SF Medicines on Childhood Pneumonia: WHO Study on Impact Model https://www.who.int/publications/i/item/9789241513432

3. Objectives

The purpose of this articlewas to describe and provide analysis of the current state of medicines and health technologies regulation in Somaliland, illustrate the capacity of the regulatory system and present recommended and immediate interventions and actions needed by the Medicines Regulatory Authority to tackle the burden of substandard and falsified medical products in Somaliland.

4. Methodology

The literature was reviewed on the issue and evidence from other accessible sources were incorporated including reports of post-marketing (PMS) surveys, assessments at national and regional levels, as well as author's experiences. In-depth analysis and presentation of the regulatory capacity and existing gaps is made to present the core regulatory functions in line with some of main indicators of the WHO Global Benchmarking Tool (WHO GBT) designed to be used for benchmarking and assessment of regulatory systems. "The GBT also incorporates the concept of 'maturity level' or ML (adapted from ISO 9004), allowing WHO and regulatory authorities to assess the overall 'maturity' of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement)"(18).

In this article, the current status and gaps of the regulatory system were presented covering key indicators and using some of the core indicators in the tool to summarize the findings and allow an element of systematic analysis. However, the article is notby it-self a report of full benchmarking assessment of the regulatory system.

5. Results and Discussion

5.1. Country Profile & the Healthcare System

The Republic of Somaliland is situated north of the equator in the Horn of Africa.The total area of the Republic of Somaliland is 176,119.2 Sq km(19). Somaliland was formerly a British protectorate and reclaimed its independence from the republic of Somalia after non-successful unity with the southern Somalia which was an Italian colony. Somaliland declared its independence from Somalia in 1991. The Somali civil war seriously affected the country politically, economically and socially.The population of Somaliland is 4.2 million where 53% live in urban areas, according to the National Report issued by the Central Statistics Department, Ministry of Planning, Government of Somaliland(19). The healthcare system was affected and the healthcare facilities were totally destroyed. The Ministry of Health Development of Somaliland is charged with health policy development and service delivery oversight functions(20).A survey in Somaliland reported there are about 21 public hospitals including six regional hospitals, 73 MCHs, 152 health posts and 7 TB centers in SomalilandThe private sector is estimated to comprise about: 80 clinics and hospitals as well as 779 pharmacies. Though reliable data is lacking, it's estimated that the private sector takes approximately 70- 75% of total medicines imports into the country.

5.2 The Medicines Regulatory System

Pharmaceutical regulation is designed to ensure safety, efficacy, and quality of the drugs available to consumers(21). The legal provisions are not available mainly National Medical Products Law which has been passed by the parliament to provide clear mandate and legal power and support the functions of the National Medicines Regulatory Authority (NMRA).

5.2.1 Legal Framework

Strengths: The country has National Medicines Regulatory Authority (NMRA) under the Ministry of Health. The National Medicines Policy (NMP) which designates NMRA and defines its functions has been formulated in 2014. Also, the National Health Policy (NHP II) which calls for establishment for NMRA has been developed by the ministry of health in 2011. The NMP and the Ministerial decree of November 2016 that establish the NMRA are the main available legal documents with provisions and statements to define regulatory framework of registration and/ or marketing authorization. Both documents recognize procedures to hold, suspend, and/or withdraw or cancel a MA in case there is/are finding(s) on quality, safety or efficacy issues. Furthermore, NMP explains the establishment of the National Pharmacy Regulatory Board (NPRB) as the regulatory framework, which will be responsible for quality control, evaluation, registration, pharmacovigilance, control of standards of production, importation and marketing. A rapid benchmarking (Assessment) of the NRA's capacity by WHO-IGAD Joint Initiative, according to the WHO GBT, was done in 2017 which found that only 16% of the total indicators for the regulatory system has been implemented.

Weaknesses: The regulatory environment is at its infancy and the government has a limited role in the pharmaceutical sector(22) The government does not provide the necessary political and economic support for the NMRA to effectively carry out its national duties. The legal provisions and guidelines are not in place to support the functions of the NMRA. There are some overlaps in the government bodies engaged in the regulation of the pharmaceutical sector and no clear boundaries of responsibilities are drawn. For instance, the Ministry of Health, National Health Professions Commission (NHPC) as well as the Somaliland's

Quality Control Commission (SQCC) have overlapping areas in respect to health facilities licensing, registration and inspections. To address this problem, a nationwide consultation forum would help to revise and amend the legal acts in place as well as exclude the conflict of authorities so do allow mutual coordination and cooperation to improve the government's capacity to regulate the health sector.

Regulatory Functions	Indicators Implemented	Expected	% Impl.	ML
01-NATIONAL REGULATORY SYSTEM (NRS)	2	10	16%	1
02-REGISTRATION AND MARKETING AUTHORIZATION	2	6	15%	1
03-VIGILANCE (PVL)	1	6	0%	1
04-MARKET SURVEILLANCE AND CONTROL (MSC)	4	6	0%	1
05-LICENSING PREMISES (LIC)	4	6	17%	1
06-REGULATORY INSPECTION (RI)	4	6	20%	1
07-LABORATORY ACCESS AND TESTING (LAT)	0	10	30%	1

Figure 6Summary of Rapid Benchmarking of the NRA by Joint WHO/IGAD Assessment, 2017

5.2.2Medicines registration (Marketing Authorization)

Medicines imported into the country are not registered for the ministry of health which increases the likelihood of SF medicines as well as those of unknown origin to circulate in the pharmaceutical supply chain. An important task for a drug regulatory authority (DRA) is to institute a system which subjects all pharmaceutical products to premarketing evaluation, marketing authorization and post marketing review to ensure that they conform to required standards of quality, safety and efficacy(23)

5.2.3 Licensing & Inspection Activities

The licensing of pharmaceutical premises and healthcare facilities is in place. However, standard operating procedures did not exist previously whereby some of the premises' licenses were not regularly issued and when in the case, initial inspection and assessment of the facility in regards to storage practices, infrastructure, human resources and procurement systems was not mandatory requirement until recently the NMRA has developed inspection tools to assess each facility as part of the licensing procedure. Moreover, Inspection guidelines and adequately trained staff to carry out inspection activities are not available. The NMRA should carry out effective inspections to ensure Good Storage Practices (GSPs) and Good Distribution Practices (GDPs) in the pharmaceutical supply chain. It's a key function of NRAs to require that medicinal products are imported, distributed and manufactured by an authorized persons as well as license and inspect manufacturing premises, importing agents, wholesalers, distributors and retailers (24).

5.2.4 Medicines Safety & Rational Use

Rational use of medicines involves their correct/proper/appropriate use so that their selection, dose, duration are according to the guidelines, suitable for clinical needs, at the lowest cost to the provider, community and the patient, and are dispensed correctly and taken properly (25). Worldwide, despite about one-third of the world's population lacks access to essential medicines, around half of all medicines are inappropriately prescribed, dispensed, or sold, and that half of all patients fail to take their medicine properly(26). Irrational over-use of medicines can stimulate inappropriate patient demand, and lead to reduced access and

attendance rates due to medicine stock-outs and loss of patient confidence in the health system(27). If medicines are irrationally used, this can result serious consequences such as increased morbidity, mortality and antimicrobial resistance.Irrational use of medicines may result in poor patient outcomes, rapidly increasing antimicrobial resistance, the spread of blood-borne infections, waste resources, and increased adverse medicine events (28)Antimicrobial resistance (AMR) occurs when microbes become resistant to medicines to which they were initially susceptible(29)Human-related causes – of antimicrobial resistance- include antimicrobial overuse and misuse in medicine(30)There were an estimated 4·95 million (3·62–6·57) deaths associated with bacterial AMR in 2019, including 1·27 million (95% UI 0·911–1·71) deaths attributable to bacterial AMR (31)Sub-Saharan Africa (SSA) experienced the greatest mortality ratefrom AMR in 2019(32)

Antimicrobials remain available without a prescription in many LMICs(33)A study conducted in North Western Ethiopia identified that rational medicine use is not achieved in terms of most components of the prescribing, patient care, and facility-specific indicators according to the World Health Organization/Network of Rational Use of Drugs (WHO/INRUD) core drug use indicators(34)There are a tremendous patterns of irrational medicines use though literature on scientific studies to measure the burden are limited in Somaliland. Also, the under regulated private sector dominated health system adds complexity to the situation. A pharmaceutical systems assessment study conducted in severely disrupted countries including Somalia, Afghanistan, the Democratic Republic of Congo and Haiti reported that informal markets, where medicines are regularly sold in market stalls and unregulated pharmacies, often accompanied by unqualified medical advice, have proliferated(35). A study on community use of antibiotics in Hargeisa highlighted the community's lack of understanding about antibiotic use (36)According to a study on drug use and associated factors conducted at Edna Adan University Hospital in Hargeisa, Somaliland, polypharmacy and overuse of brand drugs and antibiotics were prevalent in the study setting (37)This increases the risk of medication errors and antimicrobial resistance as well as puts patient safety at risk considering the lack of intact regulations to ensure the rational medicines use and safety in Somaliland.

A qualitative study on community use of antibiotics in Mogadishu, Somalia, underscored the need for education and awareness campaigns to address knowledge gaps and promote responsible antibiotic use (38). Various interventions can help addressing the issue of irrational medicines such as community education, awareness raising and educating healthcare providers through establishment of Antimicrobial Stewardship Programs (ASPs). The Infectious Diseases Society of America (IDSA) and the Society for Healthcare Epidemiology of America issued guidelines for developing institutional programs to enhance antimicrobial stewardship, an activity that includes appropriate selection, dosing, route, and duration of antimicrobial therapy (39). Effective antimicrobial stewardship programs can be financially self-supporting and improve patient care(40)A hospital based-antimicrobial stewardship program (ASP) is regarded as a globally accepted tool to address the challenge of AMR (41). The establishment of ASPs is warranted and feasible in hospitals and healthcare setting in Somaliland and can enhance effective antimicrobial prescribing and hence, address the burden of antimicrobial resistance. However, achieving this would need multi stakeholder collaboration among the health authorities, universities and health training institutions to implement stewardship programs in the country. Moreover, understanding the perspectives of pharmacists and other healthcare professionals such as their attitudes, knowledge and perceptions are key for establishing an effective ASP. Healthcare professionals (HCPs) working in hospitals should have adequate knowledge and awareness of AMR, its triggering factors, and strategies required to cope with AMR(42) In addition, inclusion of the AMR agenda in the higher pharmacy training curriculums and building capacity of the

pharmaceutical workforce related to AMR topic are some of the key interventions that would contribute to addressing the burden of AMR in Somaliland. The International Pharmaceutical Federation (FIP) published a report on AMR and Stewardship Education in 2023 which alsoincorporates findings of FIP's Survey on AMR education in which 272 respondents across all categories from 81 countries participated and covered case studies from diverse nations, such as Costa Rica, Croatia, Lebanon, Tanzania, Ireland, Norway, Nigeria, the UAE and the European Union, highlighted it is vital that the pharmaceutical workforce, including educators, practitioners, scientists and students, are equipped with the relevant and up-to-date knowledge, skills and attitudes required to avoid this pressing issue (43) One of the key results of the survey that stood out was to continue strengthening the educational components related to AMR within pharmacy curricula(43)

Furthermore, adherence to evidence-based guidelines plays a key role in promotion of rational medicines use. The principal benefit of guidelines is to improve the quality of care received by patients by promoting interventions of proved benefit and discouraging ineffective or potentially harmful interventions(44).Guidelines can also improve the consistency of care, empower patients, influence public policy, drive the development of disease performance measures and evaluations, and direct the planning of high-value interventions(45). Nationwide implementation & effective use of the evidence-based Somaliland Standard Treatment Guidelines (STGs) developed by the MoH in 2017 through the support of WHO could help appropriate therapeutic management of common diseases in line with the National Essential Package of Health Services (EPHS) core programs. Somaliland's Health service delivery is structured around the EPHS framework and health care services are delivered through five tiers: The community-level, theprimary health unit (PHU), the health center, the referral health center/districthospital, and regional hospitals(46). There are 3 levels of the STGs for each of the PHU, health center/referral health center and hospital and the guidelines were rolled out widely by the NMRA and Ministry of Health training hundreds of frontline healthcare workers in guideline use. However, the coverage of trainings needs to be expanded to cover all public health facilities and target more healthcare workers.

Though relevant data is limited available in developing countries, many studies report high burden of medication errors in the developed world. For instance, the U.S. Institute of Medicine estimated that up to 98,000 people die each year from medication errors in U.S. hospitals at a cost of up to USD 29 billion per year (47). A meta-analysis estimated that ADRs alone—excluding medication errors—killed over 100,000 people in 1994 and were the fourth to sixth leading cause of death in the United States (48). For community-acquired pneumonia, two-thirds of patients receive an excess antibiotic duration (i.e., days beyond guideline-recommended durations) at discharge, with each excess day increasing the risk of adverse antibiotic events(28).

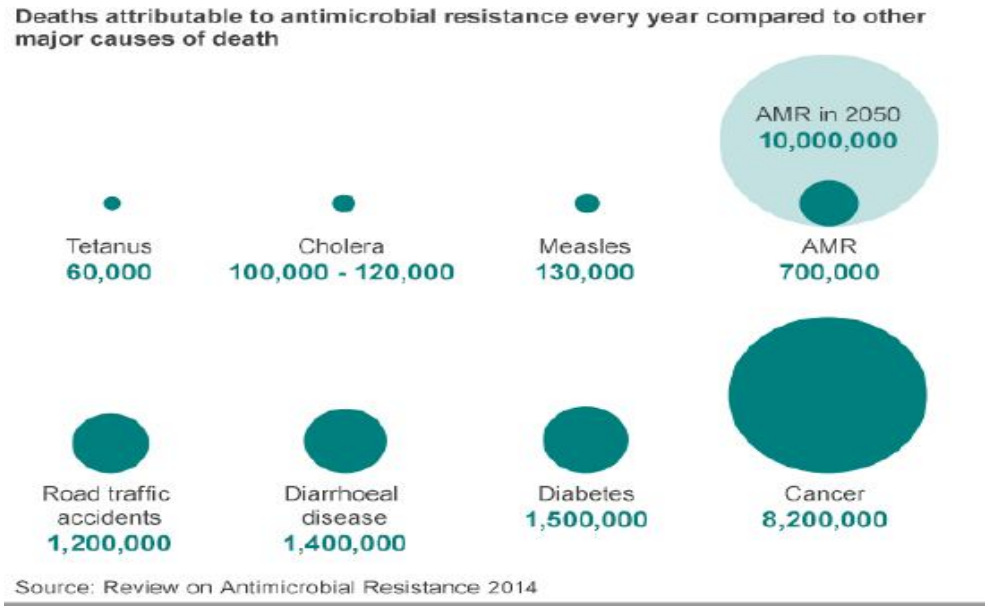

Figure 7Global attributable mortality to AMR

5.2.5 Sources of Medicines & the Pharmaceutical supply chain

The pharmaceutical sector is the least-investigated segment of the health system in Somalia or Somaliland. Importation of pharmaceutical products and medical equipment occurs at multiple land and sea border points with trade flows which results in almost complete ease of entry and exit of pharmaceutical products and the circulation of counterfeit products (49). This is a serious challenge that affects access to quality essential medicines and medical products in Somaliland like many other countries in Africa and other low resource countries. Access to medicines is defined by WHO as "*ensuring that medicines are 'available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford*"(50).The African sub-region relies heavily on the importation of medicines and raw materials for the manufacture of their medications(51). There are no local pharmaceutical manufacturing companies in Somaliland and Somalia as well whereby all medicines and other health commodities are imported. In Somalia, at least 60 percent of health services and 70 percent of the country's medicines are estimated to bedelivered by the private sector, primarily in urban areas(52). A Logistics Indicators Assessment Tool (LIAT), which focused on HIV, TB, and malaria items, reported that 81 percent of the inventory items assessed wereeither overstocked or understocked according to the facility stockholding parameters, in Somalia (52). Majority of the supply is shared among the international aid organizations and the private sector. Some International NGOs and UN agencies such as WHO, UNICEF & UNFPA provide drug donations and kits to public health facilities such as MCHs and hospitals. The MoH has Central Medical Stores(CMS) unit in Hargeisa which oversees the public supply system of medical supplies in Somaliland. The CMS oversees Central Warehouse and six regional warehouses.

Somaliland's healthcare system faces many challenges including availability of funds, access to medicines and poor supply chain capacity. One cause of these challenges is the limited national budget available for public health facilities, while a considerable share of resources for health care is provided by international donors and NGOs, there have also been some initiatives in Somaliland to encourage community involvement through cost-sharing

initiatives(53). According to a World Bank Report, conventional donor funding for the health sector in Somalia grew almost three-fold in seven years, passing from US$23 million in 2000 to US$62 million in 2006 (54). Supplies represented 29 percent of overall expenditure in the health in Somalia(54)

However, the CMS has not yet started public procurement function and there are no regional supply chain officers, the latter a challenge which hinders the operational efficiency of the public supply management system. Health facilities are irregularly supplied, with an inadequate selection of drugs through a kit system (meaning that every month there is wastage and stock-outs (22). Analysis from UNICEF and WHO indicates that 50 percent of LMICs suffered stock-outs of at least one routine immunization vaccine at the national level, in 2021where almost half of these countries experienced service interruptions owing to stock-outs in 2020, representing a 30 per cent increase from 2014(55)The use of automation and technologies are crucial in supply planning, monitoring stock levels, service utilization as well as allowing product traceability particulary detection of substandard and falsified products in the supply chain. On average, LMICs have reported using as many as34 different supply chain related information systemssimultaneously but they tend to be poorly connected orharmonized, making it hard to make informed decisions(56). In LMICs, governance structures, tools and technical capacity for active monitoring for falsification are limited and traceability systems are either non-existent or in the early stages of development(56). The use of these technologies could be even more critical during the COVID-19 where the incidents of SF medical products have exacerbated. Since the beginning of the pandemic, the Infectious Diseases Data Observatory (IDDO) identified hundreds of incidents with SF COVID-19 medical products and described some of the risks they hold for public health(57)

The storage condition of medicines is also key aspect apart from the original quality where inappropriate environmental conditions can considerably change product quality in the supply chain. This is a significant issue considering the weather conditions in Somaliland and Somalia which can be humid and hot in some regions such as the coastal areas or during rainy seasons. According to the WHO Report on Stability Conditions of Member States, Somalia is in the 30 °C/65% RH(58) and Zone IVa- Hot/humid/tropical zone according to the ICH guidelines (59). Availability of essential medicines is a critical component of health services & irregularities in their supply system hampers efforts to provide quality & effective healthcare. Inappropriate storage of essential medicines that need cold chain storage such as oxytocin and biological products is also widespread. As the national capacity in cold chain is still inadequate despite significant improvements in the last two decades, strengthening the cold chain capacity as well as training health workforce in good storage and cold chain practices would be critical in ensuring appropriate handling and preserve medicines quality. To address these challenges in the public supply sector, there is a National Supply Chain Master Plan 2014-2019 developed by the MoH in collaboration with partner agencies to guide efforts to improve the public supply sector and the implementation of the plan can help at least address some of the existing challenges in the supply chain.

Other challenges in the public procurement system includes inadequate rules, regulations and structures; public sector staff with little experience in responding to market situations; lack of decentralized supply system, absence of a comprehensive procurement policy; government funding which is insufficient and/or released irregularly; donor agencies with conflicting procurement regulations; fragmented drug procurement at provincial or district level; push supply which leads to frequent oversupplies which expire at public warehouses. Moreover, there is a problem with medicines selection at national level. The NMRA has finalized the first ever national essential medicines list (nEML) in 2019, an evidence-based document reflecting the national epidemiological patterns as well as the safety, efficacy and cost profile of medicines included, with WHO’s technical support which

can serve as the policy document to guide public procurement and donor aid. The nEML has been endorsed by the then Minister of Health Development of Somaliland after wide consultation with the D.G and technical teams. The adoption of such strategic document can help streamline procurements for the public health sector and enhance access to essential medicines in Somaliland. The Essential medicines are those that satisfy the priority health care needs of a population (60).Selection of a limited number of essential medicines as essential, taking into consideration national disease burden and clinical need can lead to improved access through streamlined procurement and distribution of quality-assured medicines(60)

5.2.6 Access to Quality Control Laboratories and the Risk of SF Medicines prevalence

There are no existing well established medicines quality testing laboratories in the country. The ministry of health has two minilab kits donated by WHO and were operational from 2009. A team of lab technicians and pharmacists were also trained abroad on how to use the kits. The minilab kit can perform basic quality testing and is effective to control the quality of medicines at ports of entry and remote areas in low resource countries. The NMRA has conducted several post-marketing quality surveillance surveys from 2009 – 2012 using the minilab covering samples collected from the private pharmaceutical supply chain. Moreover, the minilabs were re-activated with the receipt of new reagents and supplies from WHO in 2019 and were used by the NMRA to conduct post-marketing surveillance of medicines, particularly, antimalarials and antiretroviral drugs on a quarterly basis.

The Minilab kit system is developed by Global Pharma Health Fund (GPHF), a charitable organization supported by the German Merck KGaA pharmaceutical company and verifies label claims on drug identity and content and detects counterfeit medicines containing the wrong, much to high, much to low or zero levels of active ingredients(61). The Minilab covers 120 compounds taking into account medicines prevailing in developing countries for priority infectious diseases, mother & childcare, cardiovascular and diabetic disorders as well as some impurities(61). The quality standards which pharmaceuticals must comply with, as well as the methods to prove their compliance or non-compliance, are defined in the pharmacopeias, such as the International Pharmacopeia, the United States Pharmacopeia and the British Pharmacopeia. However, the equipment required for pharmacopeial analysis are expensive and delicate, requiring an appropriate laboratory and regular maintenance and operation by skilled personnel. This is a challenge for most of poor resource countries and settings like Somaliland or Somalia.

Medicine quality screening with the GPHF Minilab is a cost-effective way to contribute to the global surveillance for substandard and falsified medical products(62). Ten faith-based drug supply organizations in seven countries of Africa and Asia were each equipped with a Minilab and tested 869 medicine samples, 21 were confirmed to be substandard or falsified medical products and authors concluded that surveillance of poor-quality medicines can be carried out by local organizations in low- and middle-income countries using such simple but low-cost technology(63).There is a critical need for establishing quality control laboratories that can undertake full analytical testing of medical products quality in the country but also the utilization of the Minilab kits with maintenance of its operational capacity and scaling up its coverage nationwide and at port of entries would help monitoring of medicines quality in the pharmaceutical supply chain in Somaliland.

Table 1 Laboratory Test Results: Report of Post-Marketing Quality Surveillance of Antimalarial & Antiretroviral Medicines Samples Collected from Public Health Facilities in Hargeisa, NMRA, MoHD.2019.

Product/Category		# Samples	Quality Control Test Parameters					
			Identity		Assay (API Content)		Disintegration	
			Pass	Fail	Pass	Fail	Pass	Fail
Antimalarials	Arthemeter + Lumefantrine (AL) tabs	1	1	0	1	0	1	0
	Quinine Sulphate tabs	1	1	0	1	0	1	0
Antiretrovirals	Zidovudine + Lamivudine (3TC/ZDV tabs	1	1	0	1	0	1	0
	Zidovudine (ZDV) tabs	1	1	0	1	0	1	0

IGAD regional PMS survey conducted in 2019 to assess quality of oxytocin and amoxicillin samples collected from cross border sites of six member countries involving a total of 86 samples of oxytocin and 37 and 29 of amoxicillin DT & suspension respectively showed that 20.9 percent (18/86) of the oxytocin were substandard (8 out of 9 from Somalia) while all amoxicillin samples have passed the quality tests(64). The registration status of the samples also showed that 41.7 percent of oxytocin products and 70 percent of amoxicillin products circulating in the region were not registered by the relevant Medicine Regulatory Authorities of the region(64).

Figure 8 QC & laboratory personnel analyzing medicines samples collected from public health facilities with Minilab, Antimalarials & ARVs survey 2019, NMRA QC lab, NMRA, MoHD, Hargeisa

Table 2 Assay Results & Registration Status of Collected Samples; Adapted from IGAD-MRH Expert Working Group on PMS (2019). Results of Regional Po□-Marketing Survey to Assess the Quality of Oxytocin and Amoxicillin at IGAD Cross-Border Sites. Promoting the Quality of Medicines (PQM) Program. US Pharmacopeial Convention. Rockville, Maryland.2019.

Product Name	**Manufacturer**	**Origin Country**	**Registration Status in Somalia**	**Total Samples Tested/Product**	**Assay Result (in Samples)**	
					Passed	**Non-compliant**
Oxytocin	Opsonin Pharma Limited	Bangladesh	Not registered	9	1	8
Oxytocin	ISIS Pharmaceuticals & Chemical Works	Pakistan	Not registered			
Oxytocin	Huzhoun Pharmaceuticals	China	Not registered			
Amoxicillin suspension	Athlone Labs limited	Ireland	Not registered	2	2	0
Amoxicillin suspension	Riva Pharma	Egypt	Not registered			
Amoxicillin DT	Beyoum Pharmaceuticals	China	Not registered	6	6	0
Amoxicillin DT	Huzhoun Pharmaceuticals	China	Not registered			

Due to the lack of effective quality assurance system of medicines, it's not possible to estimate the burden of SF medicines in Somaliland. This leaves medicines imported into Somaliland to be supplied directly to consumers and patients without passing through the necessary quality screening to assure their safety, quality and efficacy. An example of quality assured products could be those supplied by some of the aid agencies such as WHO and UNICEF which have quality assurance system and procure from prequalified suppliers (suppliers undergoing thorough assessment of capacity to manufacture/supply quality and safe drugs including GMP inspections of source manufacturers). A little is known about the products supplied in the private pharmaceutical chain.Prequalification is one of the key elements in ensuring purchase and supplyof pharmaceutical products of acceptable quality(65). Prequalification of source suppliers and closed bids helps to ensure safety, quality and efficacy of procured medicines. The Expert Committee on Specifications for Pharmaceutical Preparations of the World Health Organization (WHO) adopted a Model quality assurance system for procurement agencies (MQAS) during a meeting in Geneva, Switzerland in 2005, and the MQAS have been adopted by many procurement agencies in the world while some donor organizations (including the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)) have endorsed the MQAS as part of their quality assurance policy for the procurement of pharmaceutical products with their funds(66) The MQAS could be used to build and assess capacity of the Central Procurement Agency of the MoHD which would require technical and financial resources to achieve this goal.

6. Factors that Help Circulation of SF Medicines

The poor medicines regulatory capacity in lower- & middle-income countries, in general, and Somaliland, in particular, increases the risk of circulation of SF medicines. Substandard and falsified medical products are most likely to be found where access to affordable, quality, safe and effective medical products is constrained, standards of governance are low and the tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited(67). Internet sales of medicines also contribute to the problem where illegal outlets exist selling medicines of unknown origin to the patients without medical prescriptions(7)

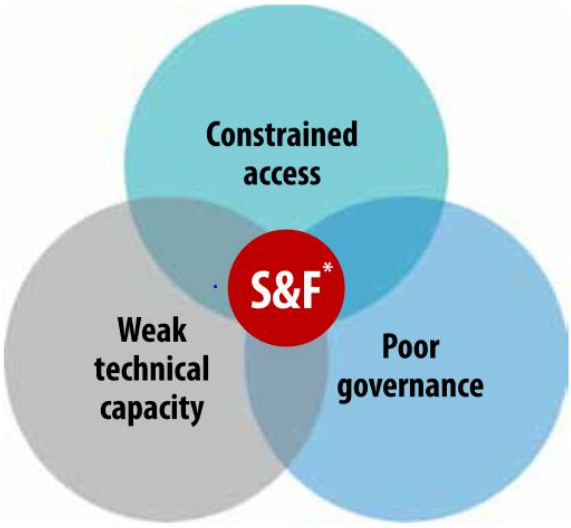

Figure 9 Contributory Factors to Emergence of SF Medical Products, adapted from WHO Global Monitoring & Surveillance System for SF Medical Products; https://iris.who.int/bitstream/handle/10665/326708/9789241513425-eng.pdf

There is a large under-regulated private pharmaceutical sector in Somaliland which lacks the capacity and intention, to some extent, to procure safe medicines from reliable sources. The lack of marketing authorization of medicines exacerbates the situation.

7. Tackling the Challenge at Global & Regional Level

Having so far discussed on the magnitude of the problem arising from substandard and falsified medicines as well as its detrimental implications, the question comes to how it can be addressed. Facing this challenge is a global shared responsibility that needs multi-stakeholder and collaborative approaches that create partnerships and coordinated platforms to enlighten the issue, increase awareness of the stakeholders and harmonize efforts to better and effective action. These approaches can encompass on prevention of the sales and distribution of SF medicines, develop mechanisms that allow early detection of these products and subsequent regulatory action and incident management by health authorities.

On a global scale, the World Health Organization spearheaded the creation of the WHO IMPACT coalition, which is supported by national medicines regulatory authorities of WHO Member States and a number of international stakeholders including Interpol, Organization for Economic Cooperation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, European Commission, Council of Europe, International Federation of Pharmaceutical Manufacturers and Associations(68). To achieve its mandate, IMPACT focuses on legislative and regulatory infrastructure, regulatory implementation, the use of technology and communication as priority areas. Also, the WHO's Global Surveillance of Medicines System (GSMS) sets the three corner stone strategies of prevent, detect and respond to address the challenge posed by the SF medical products.

Building the capacities of National Regulatory Authorities (NRAs) as well as public supply chain systems could be an effective strategy to ensure safe, effective and quality products are manufactured, procured, distributed and consumed. Creating technical information sharing and collaboration among NRAs allows early detection and unified regulatory responses at regional, continental and international level.

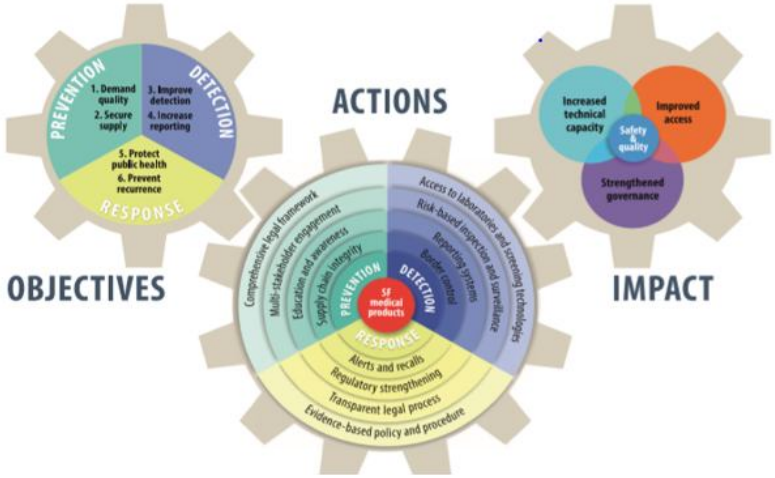

Figure 10 WHO GSMS Approaches to tackle SF Medicines;
https://iris.who.int/bitstream/handle/10665/326708/9789241513425-eng.pdf

The African Medicines Regulatory Harmonization (AMRH) initiative is a typical example of harmonized African initiative which aims to improve access to quality, safe and efficacious medicines by providing an enabling regulatory environment for pharmaceutical sector development in Africa.The African Medicines Regulatory Harmonization (AMRH) initiative was launched to accelerate access to quality, safe, effective medical products by optimizing the regulatory environment on the continent(69). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation.The AMRH initiative's goal was for NRAs within each of Africa's regional economic communities (RECs) to address this problem – *long time for drug approvals in Africa*- by coordinating their activities, relying on the work of one another and other trusted regulatory authorities, and applying other principles of smart regulation(70)The resulting improvements in regulatory efficiency would make it easier and faster for medicines manufacturers to register quality products(71)

The African Ministers of Health unanimously adopted the Treaty for the establishment of the African Medicines Agency (AMA) in Geneva, 2018. The Treaty for the Establishment of the African Medicines Agency (AMA) entered into force as of 5th November 2021, thirty (30) days after the deposit of the 15th instrument of ratification, on the 5th of October 2021, by the Republic of Cameroon at the African Union Commission (Article 38, AMA Treaty) (72)The AMA will promote the adoption and harmonization of medical products regulatory policies and standards, provide regulatory guidance and provide technical assistance on regulatory matters to countries that lack the capacity and resources to do so. The regulation of pharmaceuticals is an essential part ofimproving health care while supporting social and economic productivity of the Africanpopulation and therefore, AMA is intended to be an organ of the African Union (AU), legally mandated byMember States (MS) with the goal of increasing availability of affordable, quality, safe andefficacious medicines and other health products on the continent(73)

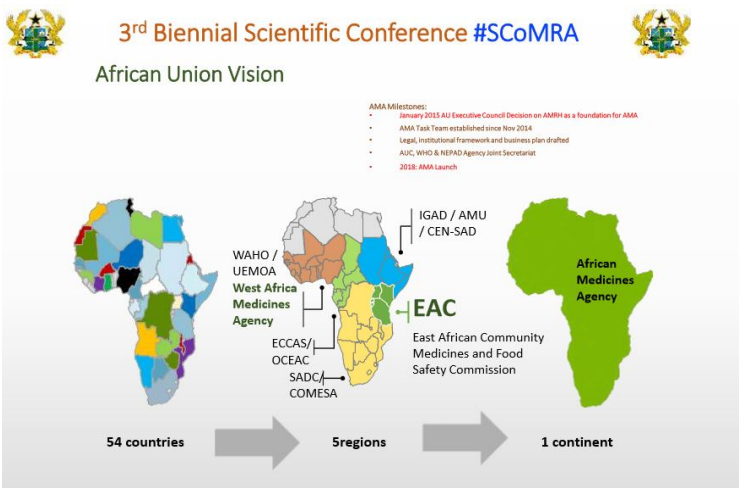

Figure 11The African Medicines Regulatory Harmonization (AMRH) Initiative: Update on Continental Progress; https://amrh.nepad.org/

AMA ratification and operationalization is currently underway with so far over 27 countries signing the treaty for establishment of AMA as of February, 2024(74). Moreover, Technical Committees (TCs) of the agency have been restructured and currently operationalization of core TCs ongoing, an effort led by the African Union Development Agency (AUDA-NEPAD). The technical committees will be responsible for carrying out specificassessments and conducting scientificreviews of dossiers, including qualityaspects, and clinical trial applications;inspection of manufacturing facilities; andproviding scientific opinion to facilitate theproper functioning of the AMA. However, there were challenges reported in the ratification process include the fact that the process is slow and there is limited understanding of the process(75)

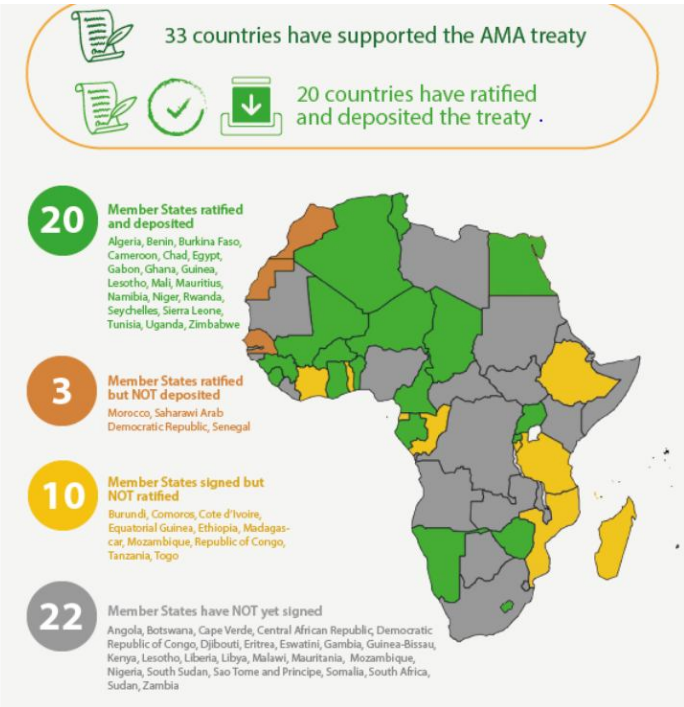

Figure 12 AMA treaty signing and ratifications, by end of 2021, Source AUDA-NEPAD*https://www.nepad.org/publication/african-medicines-agency-ama-brochure*

8. Conclusion

The following section presents key conclusions highlighting the current situation, major gaps and challenges as presented in the article. It also suggests the recommendations and specific interventions that could have future implications and help address the pressing challenges in medical products regulation in the country.Key points could be summarized as:

i. In light of the weak regulatory capacity and the porous national borders, the risk of SF medicines circulating in the pharmaceutical supply chain is very high and swift actions are needed to tackle this issue.
ii. The NRA lacks the functional capacity as well as resources and tools required to regulate medical products in the country. Also, the legal provisions are not in place.
iii. The testing laboratory capacity is limited and the Ministry has 2 minilab kits which were used to analyze drug samples collected from private sector and for quarterly samples collection for antimalarial and anti-retroviral medicines.
iv. There is a fragmented pharmaceutical supply chain system mainly dominated by the private sector while the public sector mainly relies on drug donations from UN and international aid agencies. Some of the challenges include the absence of guidelines for drug donations, cold chain infrastructure & resource challenges, drug shortages, push supply system, lack or limited use of automation and product traceability technologies as well as lack of procurement policies and guidelines.

9. Recommendations

The following are some of the recommended actions that are covering priority areas and immediate interventions that can significantly address the existing challenges:

i. Formulation of the National Medical Products Act, a law to be passed by the Parliament of Somaliland, to provide the legal framework for the National Medicines Regulatory Authority (NMRA) to regulate the import, export, distribution, sale, use and manufacture of medical products in the country.
ii. Strengthening the technical and functional capacity of the NMRA with allocation of sufficient human and financial resources as well as legal autonomy to execute its national duties.
iii. The Government of Somaliland should provide mechanisms and strategies for the implementation of the National Medicines Policy including strategies for ensuring affordability and financing schemes for essential medicines to the people of Somaliland. This could also be supported by the implementation of the National Essential Medicines List (nEML) and prioritize the use of the list to guide public procurement and donations.
iv. Development and implementation of an Institutional Development Plan (IDP) for the NRA based on a full benchmarking of the regulatory system, guiding building its capacity for 5 years period and with prioritization of core regulatory functions such as: licensing and registration of medicines and medical devices, laboratory capacity and access, post-marketing surveillance and pharmacovigilance as well as inspections and imports control.
v. Strengthening the public supply chain system by developing an effective public procurement policies and guidelines, building the supply chain capacity particularly the human resources and technical aspects to switch from the current push to pull systems, the efficient use of data, use of automated systems and technologies for supply chain monitoring, planning and product traceability.
vi. Enhancing coordination and collaboration among the key government authorities such as the MoHD, SQCC, NHPC, the Ministry of Interior and Customs Authorities as well to monitor and control drug imports and tackling substandard and falsified medical products sale and distribution in Somaliland.

The implementation of such interventions can be vital to ensure access to safe, quality & efficacious medicines and health technologies in Somaliland and will help safeguarding the public health and health security as well as contribute to achieving the national health targets in line with the national medicines policy, national health policy and strategic plans of the Ministry of Health Development of Somaliland.

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